

REMARKS

This Amendment is submitted in reply to the Non-Final Office Action mailed on February 27, 2009. A Petition for a one month extension of time is submitted herewith this Amendment. The Commissioner is hereby authorized to charge \$130.00 for the Petition for a one month extension of time and any additional fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0112843-00076 on the account statement.

Claims 12-28 are pending in this application. Claims 12-16 were previously withdrawn and Claims 1-11 were previously canceled without prejudice or disclaimer. In the Office Action, Claim 22 is objected to. Claims 18-20 and 23-28 are allowed. Claims 17 and 21 are rejected under 35 U.S.C. §102. In response, Applicants have amended Claims 17 and 28 and have canceled Claims 21-22 without prejudice or disclaimer. In view of the amendments and/or for at least the reasons set forth below, Applicants respectfully request that the objections and rejections be reconsidered and withdrawn.

Initially, Applicants note that the Patent Office has found Claims 18-20 and 23-28 to be free of art and, as such, has allowed Claims 18-20 and 23-28. See, Office Action, page 1; page 4, lines 11-12. Applicants also note that Claim 28 has been amended solely for the purpose of converting Claim 28 from a dependent claim to an independent claim. No new matter has been added to Claim 28 and Applicants submit that the allowability of currently amended Claim 28 has not changed.

In the Office Action, Claim 21 is rejected under 35 U.S.C. §102(b) as being anticipated by European Patent No. 0816380 to Goto et al. ("*Goto*"). However, Applicants note that Claim 21 has now been canceled without prejudice or disclaimer. Accordingly, Applicants respectfully submit that the rejection of Claim 21 is now rendered moot.

Accordingly, Applicants respectfully request that the rejection of Claim 21 under 35 U.S.C. §102 be reconsidered and withdrawn.

In the Office Action, Claim 17 is rejected under 35 U.S.C. §102(b) as being anticipated by European Patent No. 0786473 to Takada et al. ("*Takada*"). In contrast, Applicants respectfully submit that *Takada* is deficient with respect to Claim 17.

Currently amended independent Claim 17 recites, in part, a food material comprising an osteoprotegerin isolated from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 130 kDa. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 8, lines 3-8, originally filed Claims 1; and Figure 2. Figure 2 illustrates osteoprotegerin including a glycosylation pattern giving rise to a polypeptide having a molecular weight between the claimed range as shown by the Western Blot analysis.

The present invention is directed to the use of osteoprotegerin, which has been found to be present in human and bovine milk. The gist of the present invention resides in the provision of a particular form of osteoprotegerin, which exhibits a specific glycosylation pattern giving rise to polypeptides having a molecular weight of approximately 130 kDa. A high stability is conveyed to said protein due to this specific glycosylation pattern, such that said protein may even be taken up via the gastro intestinal tract without being degraded and all the same will be transported to its respective targets to exert its biological activity as the site. This characteristic makes said protein useful for preparing food materials and/or pharmaceutical compositions, which may be used for the treatment of diseases associated with bone remodeling and immune function. In contrast, Applicants respectfully submit that *Takada* fails to disclose or suggest every element of independent Claim 17.

Takada fails to disclose or suggest a food material comprising an osteoprotegerin isolated from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 130 kDa as required, in part, by the present claims. Since *Takada* fails to disclose or suggest the particular form of osteoprotegerin (e.g., approximately 130 kDa), *Takada*, therefore, cannot disclose or suggest the food materials comprising the protein. Consequently, *Takada* also fails to disclose or suggest the resulting effects of the compositions.

Instead, *Takada* is entirely directed to a basic protein and/or peptide composition, which may be used for example for the stimulation of osteoblastic proliferation. The composition is characterized in that it has a molecular weight distribution of said basic protein of 2.000 to

24.000 Daltons and may be isolated from milk. Further, the composition may be comprised in a cheese product or a dog food.

The Patent Office asserts that *Takada* relates to an identical protein as the present claims. However, Applicants respectfully disagree. While it may be correct that the amino acid sequences are similar, the glycosylation patterns of OPG from milk and that of the OCIF of *Takada* are different, leading to different functional properties of the protein (and to different molecular weights). Moreover, the OCIF of *Takada* was obtained from a human embryonic fibroblast IMR-90 cell culture or by recombinant methods and not from milk. That OPG can be obtained from milk is not taught or suggested by *Takada*. It appears clear that both the production in very specific fibroblast cells, which synthesize and maintain the extracellular matrix of many animal tissues, but have nothing in common with milk production or the recombinant method of production will lead to different glycosylation patterns than that of the natural glycosylation pattern seen in milk, leading to functional different properties.

This is in direct contrast to the present claims. The fact that OPG of the present claims can be obtained from milk allows applying this compound to food products since it is a compound that occurs in natural milk. Recombinant expression of OCIF makes this compound particularly useful for addition to medical preparations.

Further, upon review of *Takada*, the skilled artisan would appreciate how to prepare a basic protein concentration having a molecular weight distribution of 2.000 to 24.000 Dalton, and how to denature the composition by heat or by treatment with ethanol to achieve a positive effect on cells. See, *Takada*, column 8, Figures 1 and 3. If the protein composition is not denatured, it exhibits a clear bone resorptive activity. See, *Takada*, compare Figure 3, bars control and A. Accordingly, in the cheese product of *Takada*, the composition is denatured. Upon ingestion, such a product will degrade again in the gastrointestinal tract, reducing the composition distribution and making it more likely that the double degraded composition of the cheese product may not be as active as before. However, the solution of the present invention uses a totally different protein and approach (being native in stabilized form) by providing a stabilized osteoprotegerin (OPG) protein of approximately 130 kDa that is capable of surviving degradation in the gastrointestinal tract and showing its activity at the target site. See, specification, page 4, lines 20-31. For at least the above-mentioned reasons, Applicants

respectfully submit that *Takada* fails to disclose or suggest a food material comprising an osteoprotegerin isolated from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 130 kDa as required, in part, by the present claims.

Further, anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) (emphasis added). Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than all elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgwood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). As such, a reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found. For at least these reasons, Applicants respectfully submit that *Takada* fails to anticipate the presently claimed subject matter, and that Claim 17 is novel, nonobvious and distinguishable from the cited reference and is in condition for allowance.

Accordingly, Applicants respectfully request that the rejection of Claim 17 under 35 U.S.C. §102 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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Dated: May 29, 2009